REMARKS/ARGUMENTS

Claims 1-18 are pending in the application. Claims 1, 7, and 13 have been amended. The following discussion will concentrate on claims 1, 7, and 13 because they are the independent claims pending in the application.

Claims 1-18 were rejected under 35 U.S.C. § 103(a) as being obvious over Lai (5,549,632) in view of Swinger (6,325,792) and in view of Davidson (5,282,088). Claims 7 and 13 were provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1, 29, and 33 of Application No. 09/772,539. Applicant submits that all of these rejections have been overcome for the reasons discussed below.

I. Prior Art § 103(a) Rejection – Lai (5,549,632), Swinger (6,325,792), and Davidson (5,282,088)

Claims 1-18 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lai (5,549,632) in view of Swinger (6,325,792) and in view of Davidson (5,282,088).

Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness because, *inter alia*, the suggested combination of references must teach or suggest all claim limitations, there is no motivation to combine the references, and Davidson is non-analogous art.

The Examiner has the initial burden of presenting a *prima facie* case of obviousness. *See* MPEP §§ 2142-43; *In re Peehs*, 612 F.2d 1287 (CCPA 1980). This requires the examiner to meet three basic criteria: (1) the suggested combination of references must provide a teaching, incentive, or suggestion to combine these references; (2) the suggested combination of references must show a reasonable expectation of success from the combination; and (3) the suggested combination of references must teach or suggest **all** claim limitations. *See* MPEP §§ 2143.01-2143.03. If the Examiner fails to meet any one of these three basic criteria, he has failed to present a *prima facie* case and any rejection based on 35 U.S.C. § 103(a) is improper. In the present case, the Examiner has failed to meet any one of these three basic criteria. Accordingly, the standing rejections under 35 U.S.C. § 103(a) are improper.

A. The suggested combination of references does not teach or suggest all claim limitations because, *inter alia*, Davidson does not teach a lens that does not discolor or lose light transmittance after being subjected to *gamma* radiation

Ignoring the discussion below that Davidson cannot be properly combined with Lai and Swinger, and assuming that Davidson *could* properly be combined with Lai and Swinger, the resulting combination would not teach or suggest all the claim limitations of the present invention. As discussed above, claim 1 of the present invention is directed to an "improved applanation lens for use in an interface between a patient's eye and a surgical laser system that does not discolor or lose light transmittance when subjected to **gamma** radiation..." None of the cited references contain the limitation that the lens "does not discolor or lose light transmittance when subjected to gamma radiation."

In contrast to the claimed invention, which is directed to an applanation lens that does not lose transmittance after being subjected to **gamma** radiation (*see* claim 1: "An improved applanation lens ... that does not discolor or lose light transmittance when subjected to **gamma** radiation..."), Davidson teaches that "if the lens is made from fused silica, then it is transparent down to about 180 nanometers," which is light in the **ultraviolet** range, as acknowledged by the Examiner. (*See* Office Action dated January 31, 2003, p. 4.) Gamma radiation has wavelengths at least two orders of magnitude less than ultraviolet radiation, and is four orders of magnitude less than the wavelength disclosed in Davidson.[1]

Davidson makes no mention of gamma radiation and fails to mention any effects of gamma radiation on fused silica, let alone teach that fused silica is transparent after being subjected to gamma radiation. Indeed, in stating that the fused silica is transparent "**down to** about **180** nanometers," Davidson teaches away from the concept that fused silica would not lose transmittance after being subjected to gamma radiation, in the range of **less than 0.01** nanometers wavelength.

Lai and Swinger each disclose an "applanation plate" (Lai) and a "contact lens" (Swinger) for use in corneal surgery, but neither discusses the issue of the material losing transmittance after being subject to radiation. Accordingly, even if the three references *could* be combined (which Applicant believes would be improper, as discussed below), the

[1] Visible light has wavelengths between 7 x 10^{-7} and 4 x 10^{-7} m; ultraviolet light has wavelengths between 4 x 10^{-7} and 10^{-9} m; x-rays have wavelengths between 10^{-9} and 10^{-11} m; and gamma rays have wavelengths less than 10^{-11} m. *See The Electromagnetic Spectrum*, University of Tennessee Physics Department, *at* http://csep10.phys.utk.edu/astr162/lect/light/spectrum.html, copy attached.

resulting combination would not teach or suggest all the claim limitations of the present invention, because none of the references disclose that a lens made of high purity silicon dioxide "does not discolor or lose light transmittance when subjected to gamma radiation."

B. The suggested combination of references does not provide any teaching, incentive, or suggestion to combine these references.

A combination of prior art teachings, such as Lai, Swinger, and Davidson, cannot be shown to establish obviousness absent some teaching, incentive, motivation, or suggestion to combine the references. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988); *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577 (Fed. Cir. 1984). This teaching, incentive, motivation, or suggestion to combine the references can be found in three sources: the nature of the problem to be solved; the teachings of the prior art; and the knowledge of persons of ordinary skill in the art. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). The Examiner fails to point to any of these three sources to find the requisite teaching, incentive, motivation, or suggestion to combine the references.

There is a variety of reasons why such teaching, incentive, motivation, or suggestion is absent from any of the three sources. First, Davidson is directed to a completely different and unrelated technology than Lai and Swinger. Davidson is directed to semiconductor fabrication operations, while Lai and Swinger are directed to corneal laser surgery. *See* Davidson, col. 1, lns. 66-68; Lai, col. 1, lns.8-11; and Swinger, col. 1, lns. 15-17, respectively.

Indeed, Applicant respectfully submits that Davidson is non-analogous art. A prior art reference is analogous if the reference is (1) in the field of the applicant's endeavor or, if not, (2) the reference is reasonably pertinent to the particular problem with which the inventor was concerned. *See In re Oetiker*, 977 F.2d 1443, 1446 (Fed. Cir. 1992). Davidson does not meet either of these requirements. The present invention solves the problem of encountering non-uniform discoloration or loss of transmittance of a lens when it is sterilized using gamma radiation, thus introducing an uncontrolled variable into the system. This is a serious problem in the art of Applicant's invention because of the need to be able to focus a laser beam to precise locations in or on the cornea, and to consistently deliver a predetermined level of laser energy to that location. Namely, the present invention solves this problem by providing an applanation lens made of a material, high purity SiO_2, that resists discoloration upon prolonged irradiation by gamma rays, and is also biocompatible with corneal tissue. *See* p. 5, ¶¶ 0014-0018, and claims 1, 7, and 13. Davidson is not in the

"field of this endeavor" because the advantage of using fused silica for his spherical lens is based on its property that allows the lens to be "transparent down to about 180 nanometers wavelength" (col. 2, lns. 50-52), **not** gamma rays, and not because of its biocompatibility properties and other properties when subjected to sterilization. Indeed, it is expected that Davidson would not emphasize the biocompatibility property of fused silica, because biocompatibility is completely irrelevant in the realm of semiconductor fabrication operations. Accordingly, Davidson is also not "reasonably pertinent to the particular problem with which the inventor was concerned." Thus, Davidson represents non-analogous art and as such, cannot be combined with Lai. *See, e.g., In re Oetiker*, 977 F.2d at 1446; *In re Clay*, 966 F.2d 656 (Fed. Cir. 1992).

Secondly, Davidson does not provide anything that would further an objective of the Lai or Swinger inventions. Neither Lai nor Swinger mention anywhere the problem of finding and using a material in the "applanator plate" (of Lai) or "contact lens" (of Swinger) that has the biocompatibility properties and other properties of the present invention when subjected to sterilization by gamma radiation. Specifically, according to Lai, his "applanator plate" serves the purposes of (1) providing a positional reference for a surgical laser; (2) controlling the shape of the patient's cornea during a surgical laser procedure; and (3) providing a boundary between the epithelium and air, the contour of which can be controlled to reduce the distortion of the surgical laser beam. *See* col. 4, lns. 52-57. Further, Lai's "applanator plate" is "preferably constructed of a transparent light weight plastic, such as acrylic..." Col. 7, lns. 49-50. The "contact lens" disclosed in Swinger is "transparent to the laser energy being delivered" (*see* col. 25, ln. 67) and, in one embodiment, is a "hard material" (*see* col. 30, lns. 64-66). Swinger does not provide any other description of his "contact lens" and, like Lai, does not discuss gamma radiation or sterilization.

Thus, one skilled in the art would not, from the disclosures of Lai, Swinger, and Davidson, look to combine the three references to address the problem solved by the present invention.

Further, when the general knowledge of one of ordinary skill in the art provides the requisite motivation to combine the references, as the Examiner asserts in this case, there must be a specific understanding or technological principle within that knowledge that would motivate one with no knowledge of the invention to make the invention. *See In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998). Moreover, patent law requires that "assertions of technical facts in areas of esoteric technology must always be supported by citation of some reference

work" and "allegations of specific 'knowledge' of the prior art, which might be peculiar to a particular art should also be supported." *In re Ahlert*, 424 F.2d 1088, 1091 (CCPA 1970); *see also* MPEP § 2144.03. Thus, the Examiner cannot merely make reference to the knowledge of one skilled in the art in concluding that "it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Lai with Swinger et al. and in view of Davidson."

C. The suggested combination of references does not show any reasonable expectation of success from the combination

To satisfy the last basic criteria of *prima facie* obviousness, the Examiner must show a reasonable expectation of success from the combination of the Lai, Swinger, and Davidson references or the modification of Lai and Swinger to incorporate the teachings of Davidson. Again, the cited references do not teach or suggest the proposed combination or modification. Accordingly, no reasonable expectation of success (or synergy resulting from the combination) can be found. As discussed above, neither reference mentions the problem solved by the present invention. Lai discloses an "applanation plate" but does not discuss the necessity of the material to withstand radiation sterilization and maintain biocompatibility after sterilization. Swinger discloses the use of a "contact lens" but, like Lai, does not discuss the necessity of the material to withstand radiation sterilization and maintain biocompatibility after sterilization. Davidson is directed to a spherical microlens, less than one millimeter in diameter. Applicant respectfully notes that the requisite motivation or desirability of a combination cannot be derived from benefits resulting from the claimed combination when only the patent application at issue discloses those benefits, or any reasonable expectation of success. This is the case here.

The arguments outlined above also support Applicant's position that each of claims 2-18 is also patentable. Specifically, claims 2-6 depend from independent claim 1 and are, therefore, patentable for the reasons as set forth above with respect to claim 1. Independent claim 7 is directed to an interface including an applanation lens made of high purity SiO_2, and independent claim 13 is directed to a method for applanating a patient's eye using an applanation lens made of high purity SiO_2. For the reasons discussed above, the Examiner has not set forth a *prima facie* case of obviousness with respect to these independent claims, either. Claims 8-12 depend from claim 7, and are therefore patentable for the reasons as set forth with respect to claim 7, and claims 14-18 depend from claim 13, and are therefore patentable for the reasons as set forth with respect to claim 13.

II. Provisional Double Patenting Rejection – claims 7 and 13

Claims 7 and 13 have been provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1, 29, and 33 of copending Application No. 09/772,539. Because this is a *provisional* double patenting rejection, Applicant will respond if and when claims 1, 29, and 33 of copending Application No. 09/772,539 issue.

III. Conclusion

Thus, as discussed above, the Examiner has failed to meet any one of the three basic criteria for making out a *prima facie* case of obviousness. As set forth above, there is no motivation to combine the Lai reference (directed to corneal laser surgery) and the Davidson reference (directed to semiconductor fabrication operations). Indeed, Applicant respectfully submits that the Davidson reference is non-analogous art. Accordingly, the standing rejections of claims 1-18 under 35 U.S.C. § 103(a) are improper.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment, captioned **"Version with markings to show changes made."** Also attached is a version of the pending claims after the current amendment, captioned **"Version with currently pending claims."**

Applicant believes that no fee is due with this response. However, if an additional fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02540US1 from which the undersigned is authorized to draw. A duplicate copy of this paper is enclosed. If a Petition is required for proper submission of this Response, Applicant hereby provides said Petition and authorization of any filing or petitioner fee.

The undersigned is available for consultation if the Examiner believes such consultation will help resolve any outstanding issue or otherwise expedite the prosecution of this application.

Dated: 5/13, 2003

Respectfully submitted,

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Version With Markings to Show Changes Made

1. (Amended) An improved applanation lens for use in an interface between a patient's eye and a surgical laser system that does not discolor or lose light transmittance when subjected to gamma radiation, said improved applanation lens comprising:

[a.] a lens having an applanation surface configured to contact the eye [and applanate or flatten the anterior surface of the eye upon application of a pressure,]said lens being formed of high purity [silicone] <u>silicon</u> dioxide (SiO_2).

7. (Amended) An interface, adapted to couple a patient's eye to a surgical laser, the interface comprising:

a. an attachment apparatus adapted to overlay the anterior surface of an eye and for stable engagement to the eye;

b. an applanation lens adapted to be mounted on the attachment apparatus, said applanation lens having an applanation surface configured to contact the eye [and applanate or flatten the anterior surface of the eye upon application of a pressure,]said surface being bounded by a plane and coupled to a delivery tip of the surgical laser such that the delivery tip is referenced to the plane; and

c. said applanation lens being formed of high purity SiO_2.

13. (Amended) A method for applanating an anterior surface of a patient's eye and coupling the eye to a surgical laser, the method comprising the steps of:

a. providing an interface, the interface including a central orifice, and having top and bottom surfaces;

b. removably coupling a suction ring to the bottom surface of the interface; positioning the interface over an operative area of an eye, such that the suction ring comes into proximate contact with the surface of the eye;

c. applying a suction to the suction ring to thereby stabilize the position of the interface relative to the operative area of the eye;

d. positioning an applanation lens in proximate contact with the operative area of the

eye, said applanation lens having an applanation surface configured to contact the eye [and applanate or flatten the anterior surface of the eye upon application of a pressure,]said applanation lens being formed of high purity SiO_2; and

e. coupling the applanation lens to the interface to thereby stabilize the position of the lens relative to the operative area of the eye.